

REMARKS

These remarks are responsive to the Office Action mailed on June 24, 2009 (“the Office Action”). The Applicant thanks the Examiner for the examination of the above-referenced Application.

Status of the Claims

At the time of the Office Action, claims 1-4, 6-8, 10, 11 and 13-68 were pending, with claims 16-54 being withdrawn from consideration and claims 1-4, 6-8, 10, 11, 13-15 and 55-68 being rejected to. Claims 1, 55-59, 62, and 68 are amended herein. Claim 60 is cancelled herein. Support for these amendments may be found throughout the Specification. No new matter is being submitted.

35 U.S.C. § 112 Rejections

Claims 1-4, 6-8, 10, 11, 13-15, and 55-68 currently stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Office Action, p. 2. The Applicant respectfully disagrees with the Examiner’s contention that the specification and drawings do not support the claim language. However, in an effort to advance prosecution of the Application, the Applicant has removed the language at issue in the 35 U.S.C. § 112 rejection from independent claims 1, 55, 62, and 68.

Since the amendments to claims 1, 55, 62, and 68 obviate the rejections under 35 U.S.C. § 112, first paragraph, the Applicant respectfully requests that the rejections be withdrawn. Moreover, since the 35 U.S.C. § 112, first paragraph rejection is the only rejection outstanding with respect to claims 1-4, 6-8, 10, 11, and 13-15, Applicant respectfully submits that those claims are in condition for allowance.

35 U.S.C. § 103 Rejections

Pending claims 55-68 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Yuan, *et al.* (WO 01/52758), in view of Cotrel (U.S. Patent No. 5,154,719) and further in view of Vienney, *et al.* (WO 03/024343). Office Action, p. 3. In order to render a claim obvious, a combination of references must teach or suggest each and every claim limitation. The Applicant respectfully submits that the cited references, alone or combined, fail to render the present invention obvious.

The Examiner contends it would have been obvious to modify the extension flange on the lower cap in the modified invention of Yuan, in view of Cotrel, and further in view of Vienney, to have a width that is substantially equal to the width of the rod and channel. The Examiner suggests that one of ordinary skill in the art would have combined these references “in order to keep the lower cap in proper orientation with the rod.” Office Action, p. 5. Such a suggestion is insufficient to establish a *prima facie* case of obviousness since it provides no reasoning why one of ordinary skill in the art would **combine** the teachings of the references. *See e.g.* MPEP § 2143.01 IV; *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993).

One of ordinary skill in the art would not have combined the teachings of Yuan and Cotrel with Vienney “in order to keep the lower cap in proper orientation with the rod,” since Yuan already taught structure to keep the lower cap in proper orientation with the rod. Namely, Yuan teaches that the “lower portion 220b of locking cap 220 is configured for cooperative reception within the cylindrical vertical channel 227 of head portion 222 . . . [thus,] a positive mating relationship is achieved between the lower portion 220b of the locking cap 220 and vertical channel 227. As a result, the axial

portion of lower portion 220b becomes **fixed with respect to** the head portion 222 and the **spinal rod 212.**" Yuan, p. 18. Yuan suggests that extension flange 302 may be used as an aid "in the alignment and positioning of the lower cap portion with respect to the spinal rod." *Id.* However, the use of the extension flange is limited to aligning the lower cap appropriately so that the lower portion thereof may be in mating relationship with the vertical channel and the lower portion thereof and the vertical channel may cooperatively maintain the lower cap in a fixed axial orientation with respect to the spinal rod.

One of skill in the art would not have attempted to widen the extension flange of Yuan to keep the lower cap in proper orientation since the mating relationship between the vertical channel and the lower portion of the lower cap already accomplishes that result. Moreover, one of skill in the art would recognize that in the configuration of Yuan it would be beneficial to **not** have the extension flange have a width that is substantially the same as the width of the rod and channel. Having such a width might prevent a surgeon from making appropriate axial adjustments of the lower cap to ensure an appropriate mating relationship between the vertical channel and the lower portion of the lower cap. In other words, an extension flange with a wide width may interfere with sidewalls of the head portion while attempting to obtain an appropriate mating relationship between the vertical channel and the lower portion of the lower cap, thereby making it difficult or potentially impossible to do so.

The Examiner's stated reasoning for combining the cited references is illogical in light of the teachings of the references and does not constitute an objective reason for combining the teachings of the references. As a result, a *prima facie* case of obviousness

has not been established and the Applicant therefore requests that this rejection be withdrawn.

Moreover, even if one of skill in the art had an objective reason to widen the extension member of Yuan, they would not look to Vienney to do so. The Examiner contends Vienney suggests a lower cap (3) having a width that is substantially equal to a rod (2) and channel (12) in order to keep the lower cap in proper orientation with regards to the rod. Office Action p. 5. However, Vienney does not teach an **extension** member as recited by claims 55 and 62 or a second orientation means **extending** from said lower cap as recited by claim 68 and would thus not be looked to when modifying an extension member. Rather, the lower cap (3) of Vienney is substantially rectangular in cross section and does not contain any structure extending therefrom. The structure cited by the Examiner is the same width as the remainder of the lower cap 3 and cannot be construed as **extending** from anything.

Applicant has amended independent claims 55 and 62 to highlight that the claims in fact recite an **extension** member and are therefore distinguishable over the cited references. For at least the reasons set forth herein, the Applicant respectfully submits that the cited references fail to render obvious independent claims 55, 62, 68 and any claim depending therefrom. Thus, the Applicant respectfully requests that this rejection be withdrawn.

Moreover, the combination of Yuan and Cotrel is improper. The examiner contends that substituting the locking engagement of Yuan, in view of Cotrel would yield the predictable result of creating a locking engagement between the locking assembly and housing. Office Action p. 3. Such a suggestion is insufficient to establish a *prima facie*

case of obviousness since it provides no reasoning why one of ordinary skill in the art would **combine** the teachings of the references. *See e.g.* MPEP § 2143.01 IV; *Ex parte Levengood*. Moreover, even if Yuan and Cotrel were combined, the teachings would be insufficient to render the claims *prima facie* obvious since the combination of Yuan and Cotrel would change the principle of operation of Yuan. *See e.g.* MPEP § 2143.01 VI; *In re Ratti*, 270 F.2d 810 (CCPA 1959).

One of ordinary skill in the art, having the benefits of the teachings of Yuan would not look to any art that utilizes a threaded fastener in order to create a **locking** engagement between the locking assembly and the housing. Yuan explicitly teaches that threaded fasteners are unsuitable for creating a sufficient and lasting locking engagement between the locking assembly and housing and proposes a non-threaded fastener to remedy this problem. In particular, Yuan suggests that threaded fasteners can become loosened under the influence of cyclically applied loads commonly encountered by the spinal column and that during assembly threaded fasteners can often cause damage to both the fastener and the housing. Yuan, pp. 2-3.

As a result, one of ordinary skill in the art, having the benefit of Yuan, would have no reason to look to art that employs threaded fasteners in order to create a locking engagement between the locking assembly and housing, as suggested by the Examiner. Rather, one of ordinary skill in the art, having the benefit of Yuan, would be motivated to avoid any such art out of fear of creating an engagement between the locking assembly and housing that may become loosened and/or that may cause damage to the fastener and/or housing.

Moreover, the combination of Yuan and Cotrel would change the principle of operation of Yuan. Yuan proceeds under the basic principle that threaded fasteners are inadequate and that a cammingly engageable locking assembly is necessary to create a sufficient and lasting locking engagement between the locking assembly and housing. Additionally, combining Cotrel with Yuan would require a substantial reconstruction and redesign of the elements of Yuan. Therefore, modifying the cam structure of Yuan to employ a threaded fastener would change the basic principle under which Yuan was designed to operate.

The Examiner's stated reasoning for combining the cited references is illogical in light of the teachings of the references and does not constitute an objective reason for combining the teachings of the references. Moreover, the combination of the references would change the principle of operation of the primary reference. As a result, a *prima facie* case of obviousness has not been established and the Applicant therefore requests that this rejection be withdrawn.

In addition, the Applicant respectfully submits that the Office Action fails to address the "wherein when said first orientation means is properly oriented with respect to said housing and said upper cap opening is properly oriented with respect to said second orientation means, said male threads will align with said female threads to prevent cross threading" (the "Timing Structure") feature of independent claim 68. The Office Action is silent with respect to this feature of claim 68 and, as a result, a *prima facie* case of obviousness has not been established for claim 68. The Applicant respectfully submits that the cited references fail to disclose this feature of claim 68 and therefore do not

render claim 68 obvious. Thus, the Applicant respectfully requests that this rejection be withdrawn.

Applicant submits that lines 23-25 of amended claim 55 and lines 17-19 of amended claim 62 also recite structure similar to the Timing Structure and those claims should likewise be allowed since the cited references fail to disclose such structure. Applicant notes that lines 11-16 and 24-25 of claim 55 and lines 18-19 of claim 62 are amended herein to correct errors contained in prior versions of these claims. The amended claim 55 and claim 62 correctly recite respective structure that is similar to the Timing Structure.

CONCLUSION

The Applicant respectfully submits that the application is in condition for allowance, and reconsideration and notice of allowance are respectfully requested. If the Examiner believes that prosecution might be advanced by discussing the application with the Applicant's counsel, in person or over the telephone, the Applicant's counsel would welcome the opportunity to do so.

Respectfully submitted,

MIDDLETON REUTLINGER

Date: December 23, 2009

/ Scott W. Higdon /
Scott W. Higdon
Registration No. 64,065
401 South Fourth Street
2600 Brown & Williamson Tower
Louisville, KY 40202
(502) 625-2777 direct phone
(502) 561-0442 fax
shigdon@middreut.com